

**In the United States Court of Federal Claims**

**OFFICE OF SPECIAL MASTERS**

**No. 18-1001V**

Filed: March 29, 2024

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MERILYNNE DELIO,

Petitioner,

v.

SECRETARY OF HEALTH AND  
HUMAN SERVICES,

Respondent.

\*\*\*\*\*

*Amy Senerth*, Muller Brazil, LLP, Dresher, PA, for Petitioner

*Bridget Corridon*, U.S. Department of Justice, Washington, DC, for Respondent

TO BE PUBLISHED

Influenza (“flu”) Vaccine; Shoulder Injury  
Related to Vaccine Administration  
(“SIRVA”); Dismissal Decision

**DECISION ON ENTITLEMENT<sup>1</sup>**

**Oler**, Special Master:

On July 12, 2018, Merilynne Delio (“Ms. Delio” or “Petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*<sup>2</sup> (the “Vaccine Act” or “Program”). The petition alleges that the Petitioner developed a shoulder injury related to vaccine administration (“SIRVA”) as a result of the flu vaccine she received on November 9, 2016. Pet. at 1.

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<sup>1</sup> Because this Decision contains a reasoned explanation for the action in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Upon review of the evidence in this case, I find that Petitioner has failed to preponderantly demonstrate that the vaccine she received caused her condition. The petition is accordingly dismissed.

## **I. Procedural History**

Petitioner filed her petition on July 12, 2018. Pet., ECF No. 1. Ms. Delio also filed supporting medical records and an affidavit with the petition. Exs. 1-6. Petitioner filed a supplemental affidavit on August 7, 2018 (Ex. 7) and additional medical records on November 26, 2018 (Ex. 11) and March 5, 2019 (Ex. 12).

Respondent filed his Rule 4(c) Report on June 17, 2019. Resp't's Rep.; ECF No. 21. Respondent argued that this case is not appropriate for compensation because the medical records do not reflect that the onset of Petitioner's shoulder pain occurred within 48 hours of vaccination. Resp't's Rep. at 7.

This case was assigned to my docket on July 23, 2019. ECF No. 25.

I held a status conference on September 25, 2019 where I indicated that I "viewed onset of shoulder pain to be around December 2016, after the December 14, 2016 medical visit at which Petitioner denied any shoulder pain." Scheduling Order dated Sept. 26, 2019, ECF No. 29. Petitioner indicated that she wanted to seek the opinion of an expert. *Id.* I granted her request informing counsel that "any expert opinion should consider my views regarding onset." *Id.* Furthermore, I "directed counsel to share this Order with experts willing to opine in this matter." *Id.*

On November 25, 2019, Petitioner filed an expert report from Naveed Natanzi, DO as well as supporting medical literature. Exs. 13, 14A-14M. In Petitioner's expert report, Dr. Natanzi began his analysis stating that Petitioner "presented with right shoulder pain that began immediately after an influenza vaccination in her right arm on 11/9/16." ECF No. 28. Because this statement was inconsistent with my preliminary views regarding onset expressed during the September 25, 2019 status conference, I issued an order on November 26, 2019, requesting that Petitioner's expert respond to the following question: "Assuming shoulder pain began sometime in December 2016 (after December 14, 2016), do you believe Petitioner's flu shot caused her pain? Please explain your answer." *See* Scheduling Order dated Nov. 26, 2019, ECF No. 29.

Petitioner filed a second expert report on January 28, 2020. Ex. 15. In this report, Dr. Natanzi stated that "If I were to assume that Ms. Delio's right shoulder pain began sometime after 12/14/16 it would make a SIRVA injury much less likely." Ex. 15 at 1. Dr. Natanzi went on to reiterate his position that Petitioner's shoulder pain likely did start immediately after her vaccination. *Id.* His reasons for this were 1) she recounted immediate pain post-vaccination in her affidavit; 2) in her affidavit, she explained why she did not discuss her symptoms with Dr. Hansen on November 14, 2016 or December 14, 2016; and 3) there is no alternate explanation for her shoulder pain. *Id.*

Petitioner filed updated medical records on April 22, 2020 (Ex. 16) and June 25, 2020 (Ex. 17).

On October 2, 2020, Respondent filed an expert report from Dr. Geoffrey Abrams along with supporting medical literature. Exs. A, B, A-1-A-9. On October 27, 2020, Petitioner filed a third expert report from Dr. Natanzi. Ex. 18.

I held a status conference on April 1, 2021 where I discussed the possibility that I rule on the record concerning the issue of onset. *See* Scheduling Order dated April 1, 2021, ECF No. 44. Respondent's counsel indicated that a ruling on onset would likely help to move the case forward. *Id.* Ms. Senerth stated she had to confer with her client regarding whether she was amenable to an onset determination. I ordered Petitioner to file a status report in 10 days outlining her position. *Id.*

On April 12, 2021, Petitioner filed several affidavits. Exs. 19-21. She filed a status report on April 13, 2021 indicating that she was amenable to an onset determination on the existing record. ECF No. 46.

Petitioner filed a motion for a ruling on the record concerning onset on June 15, 2021.<sup>3</sup> ECF No. 48. Respondent filed a response on November 1, 2021. ECF No. 54. I issued my onset ruling on December 20, 2021. In that ruling, I determined that Petitioner experienced right shoulder pain between December 14, 2016 and January of 2017. ECF No. 55. I gave Petitioner until January 20, 2022 to file a status report indicating how she intended to proceed based on the facts articulated in my ruling. *Id.*

In a status report dated January 20, 2022, Petitioner stated that she intended to file a supplemental expert report. ECF No. 56. I conducted a status conference on January 25, 2022. During this conference, I asked Petitioner's counsel what an additional report from Dr. Natanzi would add, given that he had previously stated: "If I were to assume Ms. Delio's right shoulder pain began sometime after 12/14/16 it would make a SIRVA injury much less likely." Ex. 15 at 1; *see also*, ECF No. 57. Petitioner's counsel indicated that an additional expert report would help clarify Dr. Natanzi's opinion. ECF No. 57. I gave Petitioner until February 24, 2022 to file a supplemental expert report. *Id.*

Petitioner filed Dr. Natanzi's fourth expert report on March 17, 2022. Ex. 22. Dr. Natanzi stated that "While it is true that shoulder pain that begins a month or two post-vaccination makes a SIRVA injury much less likely, in my opinion, this case is an exception." Ex. 22 at 2.

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<sup>3</sup> Although the parties discussed a ruling on onset during the April 1, 2021 status conference, and Petitioner indicated that she was "amenable to an onset determination based on the record" in her status report filed on April 13, 2021 (ECF No. 46), Petitioner filed a brief requesting that I issue an entitlement ruling. (*See* Pet'r's Mot. at 7-8, stating, "Therefore, Petitioner respectfully requests that this Court find that Petitioner has demonstrated by a preponderance of the evidence that [s]he suffered a left shoulder (SIRVA) "Table" injury, and thus is entitled to a presumption of causation. Alternatively, should this Court find that Petitioner does not meet the criteria to establish a Table claim, Petitioner respectfully requests that this Court find that the evidence in this case demonstrates that Petitioner suffered a right shoulder injury caused-in-fact by the flu shot administered on November 9, 2016." ). I elected to rule on the factual issue of onset, as originally discussed on April 1, 2021. *See* Scheduling Order dated April 1, 2021, ECF No. 44; ECF No. 55.

I conducted a status conference on June 22, 2022 where I informed the parties that I planned to file Court Exhibit 1001 into the record. ECF No. 64; Hesse et al., *Risk for Subdeltoid Bursitis After Influenza Vaccination A Population-Based Cohort Study*, 173 ANNALS OF INTERNAL MEDICINE 4, 253-61 (2020) (hereinafter “Hesse”). I gave the parties 30 days to indicate whether they intended to file a response to Court Exhibit 1001. *Id.* Neither party elected to do so. ECF Nos. 66, 68.

I then set a briefing schedule and the parties filed their respective briefs on entitlement. ECF Nos. 70, 71. The parties filed a joint status report indicating the record was complete on April 27, 2023. ECF No. 72. This matter is now ripe for an adjudication.

## II. Relevant Medical Records

Petitioner had a cervical fusion in 2003 and a right rotator cuff surgery in 2001. Ex. 4 at 1.

On October 21, 2016, Petitioner visited Dr. Thomas Hansen complaining of “right elbow pain that began around January 2016.” Ex. 4 at 1. Dr. Hansen assessed her with right lateral epicondylitis and carpal tunnel syndrome; he recommended a right lateral epicondyle debridement and carpal tunnel release. *Id.* at 2. Petitioner had these procedures performed on November 1, 2016. *Id.* at 31-32.

Petitioner received her flu vaccine in her right deltoid on November 9, 2016. Ex. 1 at 1.

On November 14, 2016, Petitioner visited Dr. Hansen for a follow-up appointment after her surgery. Ex. 4 at 3. She reported some slightly limited range of motion in the elbow, but denied having “numbness, swelling, or trouble sleeping secondary to pain.” *Id.* Petitioner denied experiencing shoulder pain. *Id.* Her sutures were removed during this visit. *Id.* at 4.

Petitioner visited Dr. Hansen on December 14, 2016 for a six week post-op visit. Ex. 4 at 5. She indicated that her pain had increased lately. *Id.* She described pain in her right hand that was “‘burning’, ‘sensitive’, and an intermittent feeling of an electric current throughout her hand.” *Id.* She also described her right elbow pain as squeezing. *Id.* Petitioner indicated she had trouble sleeping secondary to pain. *Id.* She denied numbness, swelling, or limited range of motion. *Id.* Petitioner again affirmatively denied having shoulder pain. *Id.*

On January 10, 2017, Petitioner presented to Avondale Family Care for fever and body aches. Ex. 2 at 29. She tested positive for the flu and was given Tamiflu. *Id.* Petitioner denied experiencing muscle aches, painful or swollen joints, weakness, and loss of strength. *Id.* at 30-31.

Petitioner returned to Avondale Family Care on February 8, 2017 for a diabetes follow-up appointment. Ex. 2 at 25. Petitioner reported she was “having R shoulder pain now” and that she was “still healing from elbow.” *Id.* Petitioner received a cortisone injection in her right shoulder. *Id.* at 27.

On April 8, 2017, Petitioner had an MRI of her right shoulder. Ex. 4 at 36. The history indicates: “Pain for 4 months. Throbbing pain. Keeps her up at night. No known trauma. Previous rotator cuff surgery of the right shoulder.” *Id.* The impression included “findings highly suspicious for chronic calcific tendinitis of the right shoulder involving the supraspinatus tendon”; “there is a questionable tiny partial-thickness articular surface tear of supraspinatus tendon”; “mild subacromial-subdeltoid bursitis”; and prior acromioplasty with partial resection of the distal clavicle. *Id.*

On May 10, 2017, Petitioner presented to Dr. Hansen with complaints of right shoulder pain. Ex. 4 at 7. The HPI notes “the patient complains of right shoulder pain has been present since January of 2017 and is not the result of any accident, injury, or trauma.” *Id.* Petitioner described her pain as “dull, with intermittent sharpness, burning, stabbing, throbbing pain.” *Id.* Dr. Hansen assessed Petitioner with bursitis. *Id.* at 8.

Petitioner returned to Dr. Hansen on December 27, 2017. Ex. 4 at 9. She complained of pain in her right shoulder and requested a cortisone injection. *Id.* She told Dr. Hansen that her pain had been present since “approximately November of 2016.” *Id.* Petitioner told Dr. Hansen that her pain was not the result of any accident, injury, or trauma. *Id.* She also described left elbow and left forearm pain present since May of 2017. *Id.* Petitioner had positive impingement signs, full range of motion, and some tenderness over the AC joint. *Id.* at 10. Dr. Hansen assessed Petitioner with bursitis. *Id.* He administered a cortisone injection. *Id.*

On January 18, 2018, Petitioner had a PT evaluation for right shoulder pain and left medial elbow pain. Ex. 4 at 54. During this visit, Petitioner stated that “she rec’d a flu shot in her right arm on November 8, 2016 that caused her increased shoulder pain. . . . Since flu shot, her pain has gotten worse. She waited to see if her pain would improve but it did not.” *Id.* On February 5, 2018, Petitioner was discharged from PT because she did not return for her scheduled appointments. *Id.* at 52. No other pertinent medical records have been filed.

### **III. Affidavits**

#### **A. Petitioner’s First Affidavit**

Petitioner signed her first affidavit on June 5, 2018. She averred that she received a flu vaccine on November 9, 2016. Ex. 6 at 1. Petitioner stated that she had undergone rotator cuff repair in 2004, but that at the time of vaccination, she had no shoulder pain. *Id.* She further averred that she experienced pain in her right shoulder “immediately after vaccination.” *Id.*

#### **B. Petitioner’s Second Affidavit**

Petitioner signed her second affidavit on July 24, 2018. In this document, she stated that on November 1, 2016, she underwent right carpal tunnel release and right lateral epicondyle release. Ex. 7 at 1. She stated that she specifically recalled the day of her vaccination “because of the severe pain that the shot gave me right away.” *Id.* Petitioner described it as “[t]he kind of pain you don’t forget.” *Id.* Petitioner described that she was sitting in a chair while the nurse stood and administered the vaccine. *Id.* at 2. Petitioner described that immediately following vaccination, she

had pain in her right shoulder. *Id.* She averred that she told the nurse how much pain she was experiencing. *Id.* “The nurse’s response was that it could be due to the surgery I had.” *Id.* Petitioner drove herself home and used ice on her shoulder for the rest of the day. *Id.*

Petitioner averred that she continued to experience pain from the shot as she recovered from her surgery. Ex. 7 at 2. She hoped the pain would go away, but it did not. *Id.* Petitioner explained why she did not mention her shoulder pain to Dr. Hansen on November 14, 2016 or December 14, 2016. She stated: “I thought my shoulder pain could have originated from my underlying surgery because that is what the nurse who administered the vaccine told me.” *Id.* She stated that after she recovered from her November 1 surgery and her right shoulder pain continued, she decided to tell her PCP she had been experiencing right shoulder pain since the flu vaccine. *Id.*

### **C. Petitioner’s Third Affidavit**

Petitioner signed her third affidavit on December 23, 2019. In this document, Petitioner stated that she reviewed Dr. Hansen’s notes from her May 10, 2017 medical appointment. Ex. 21 at 1. She opined that these notes indicate that her right shoulder pain began in January because “I told Dr. Hansen that my pain had increased and that I was having arm and shoulder pain.” Petitioner further stated that “I thought this pain was part of the healing process because the nurse that gave me the flu shot told me that the pain I felt with the injection was because of my surgery.” *Id.*

### **D. Affidavit of Jennifer Guerrero**

Jennifer Guerrero signed her affidavit on December 23, 2019. She is Petitioner’s daughter. Ex. 19 at 1. Ms. Guerrero stated that although she was not with her mother when she received the flu vaccine, she saw her that evening. *Id.* Ms. Guerrero stated that Petitioner remarked about how much pain she was in from the flu vaccine. *Id.* She also recalls her mother telling her that the nurse who administered the vaccine attributed Petitioner’s pain to her surgery. *Id.* at 2.

### **E. Affidavit of Patrick Delio**

Patrick Delio signed his affidavit on December 24, 2019. He is Petitioner’s husband. Ex. 20 at 1. Mr. Delio stated that he was at work when Petitioner received her flu shot. *Id.* He further stated that Petitioner called him from the parking lot in tears after she received her vaccination. *Id.* According to Mr. Delio, “[s]he told me how painful the shot was and that the pain was not letting up.” *Id.* When he got home, Petitioner was still in pain. *Id.* She told him that her surgery was not giving her any issues, but that she had pain in her shoulder going down her arm. *Id.*

## **IV. Expert Qualifications and Reports**

### **A. Petitioner’s Expert: Naveed Natanzi, DO**

Petitioner submitted four expert reports from Naveed Natanzi, DO. Ex. 13 (hereinafter “First Natanzi Rep.”); Ex. 15 (hereinafter “Second Natanzi Rep.”); Ex. 18 (hereinafter “Third Natanzi Rep.”); Ex. 22-1 (hereinafter “Fourth Natanzi Rep.”).

Dr. Natanzi is board certified by the American Academy of Physical Medicine and Rehabilitation and is board-eligible by the American Board of Pain Management. Ex. 14A at 1 (hereinafter “Natanzi CV”). Dr. Natanzi received a Bachelor of Arts in Biological Studies at the University of California, Santa Barbara in 2007, and attended medical school at Western University of Health Sciences, where he received a Doctor of Osteopathy in June 2012. *Id.* at 2. Dr. Natanzi completed an internship at Downey Regional Medical Center from 2012-2013, then completed his residency in physical medicine and rehabilitation at the University of California, Irvine from 2013-2016. *Id.* at 1. Dr. Natanzi completed a fellowship at the Bodor Clinic in Napa, California from January 2017-August 2017. *Id.*

From 2017-2018, Dr. Natanzi worked at the Pasadena Rehab Institute as an attending physician specializing in interventional pain management. Natanzi CV at 1. In November 2017, Dr. Natanzi founded the Regenerative Sports and Spine Institute, and since April 2018, Dr. Natanzi has been a staff physician at the VA Long Beach Healthcare System. *Id.* Dr. Natanzi has authored seven publications and has conducted a double-blind research study. *Id.* at 3.

### **B. Respondent’s Expert: Dr. Geoffrey Abrams**

Respondent filed one expert report from Dr. Geoffrey D. Abrams. Ex. A (hereinafter “Abrams Rep.”).

Dr. Abrams received a Bachelor of Arts in Human Biology with a concentration in Neuroscience from Stanford University in 2000. Ex. B at 1-2 (hereinafter “Abrams CV”). He received his medical degree from the University of California, San Diego in 2007. *Id.* at 1. He completed a surgical internship at Stanford University in 2008. *Id.* Dr. Abrams completed his residency at the Department of Orthopedic Surgery at Stanford University Hospital and Clinics in 2012, and a fellowship at Rush University Medical Center in 2013. *Id.*

Dr. Abrams is board certified in Orthopedic Surgery, with a subspecialty in Orthopedic Sports Medicine. Abrams CV at 2. He is licensed to practice medicine in Illinois and California and is a California Fluoroscopy Supervisor and Operator. *Id.* He holds academic appointments at the Stanford University School of Medicine and the Veterans Administration Hospital of Palo Alto. *Id.* at 1.

Dr. Abrams has published seventy-two peer-reviewed publications as well as a number of peer-reviewed short communications and book chapters. Abrams CV at 2-22. He serves as the head team physician for several of Stanford University’s varsity teams and is an assistant team physician for the Golden State Warriors and the San Francisco 49ers. He has given numerous lectures on the topic of orthopedics. *Id.* at 22-28.

### **C. Dr. Natanzi’s First Expert Report**

Petitioner filed Dr. Natanzi’s first expert report on November 4, 2019. Dr. Natanzi stated his theory of the case as follows: (1) an inadvertent overpenetration of the vaccine needle resulted in (2) bursal and/or rotator cuff penetration, which caused (3) immediate pain, limited range of

motion and discomfort. Petitioner's vaccine then (4) interacted with naturally -occurring antibodies from a prior vaccination, which resulted in an exaggerated, robust, and prolonged inflammatory response resulting in (5) bursitis and rotator cuff impingement syndrome. First Natanzi Rep. at 9.

Dr. Natanzi stated that "at the time of vaccination, [Petitioner's] right arm was in a resting position on an examination table. Ms. Delio was seated and the administering provider was standing. The exact injection location on the right deltoid muscle was not recorded." First Natanzi Rep. at 7.

Dr. Natanzi described SIRVA as "a relatively uncommon phenomenon" that is unfamiliar to most medical professionals. First Natanzi Rep. at 8. He further described that "most people are unaware that a vaccination can cause significant shoulder dysfunction, and they often do not inherently associate adverse symptoms with a vaccination. This lack of knowledge and understanding of SIRVA oftentimes results in discrediting vaccines as sources of post-vaccination shoulder pain." *Id.* Dr. Natanzi posited that this may account for the fact that Petitioner did not mention shoulder pain in her medical visits on November 14, 2016 and December 14, 2016. *Id.*

Dr. Natanzi discussed Petitioner's previously existing medical conditions, to include her history of right shoulder pain and her fibromyalgia diagnosis. First Natanzi Rep. at 7. With respect to prior shoulder pain, Dr. Natanzi acknowledged that Petitioner had a prior history of right shoulder pain that required rotator cuff surgery in 2004. *Id.* He noted that she had not complained of right shoulder pain since that time, and accordingly opined that "her past history of shoulder injury had no contribution to the post-vaccination pain." *Id.* Dr. Natanzi similarly disputed a connection between Petitioner's fibromyalgia and her shoulder pain. He stated that fibromyalgia symptoms are typically "diffuse and exist throughout the body" whereas the symptoms experienced by Petitioner in the shoulder were "focal and isolated." *Id.*

Based on Dr. Natanzi's review of the medical records, he believed that Petitioner's shoulder pain began "immediately post vaccination" and that this presentation meets "the temporal relationship requirements of SIRVA." First Natanzi Rep. at 8. Dr. Natanzi credited Petitioner's statements in her affidavits describing immediate pain post vaccination. *Id.*

Dr. Natanzi noted that Petitioner's exam on May 10, 2017, where Dr. Hansen observed decreased range of motion, positive impingement signs, and tenderness over the rotator cuff are "hallmark clinical symptoms of a SIRVA injury." First Natanzi Rep. at 9. Dr. Natanzi further noted that MRI finding of partial thickness tearing and bursal fluid accumulation are common in cases of SIRVA. *Id.*

Dr. Natanzi opined that Petitioner's condition was due to the fact that her flu vaccination was improperly administered. First Natanzi Rep. at 9. Dr. Natanzi stated that the "risk of adverse reactions and overpenetration is least when both the patient and administering provider are seated and the arm is fully exposed, abducted, and flexed to 60 degrees with the hand resting on the ipsilateral hip." *Id.* Dr. Natanzi stated that this sub-optimal vaccination procedure made it "increasingly likely" that inadvertent overpenetration of the needle caused a SIRVA injury in Petitioner. *Id.*

Dr. Natanzi concluded his report by opining that “the outlined temporal relationship of symptoms to the vaccine and the absence of any pre-vaccination shoulder dysfunction” make it more likely than not that Petitioner’s November 9, 2016 vaccination caused her to develop a SIRVA. First Natanzi Rep. at 10.

#### **D. Dr. Natanzi’s Second Expert Report**

Petitioner submitted a second one-page report from Dr. Natanzi on January 28, 2020. Second Natanzi Rep. This report responded to my request that Dr. Natanzi assume that Petitioner’s shoulder pain began between December 14, 2016 and January 2017.

In this report, Dr. Natanzi stated that “If I were to assume that Ms. Delio’s right shoulder pain began sometime after 12/14/16 it would make a SIRVA injury much less likely.” Second Natanzi Rep. at 1. Dr. Natanzi went on to reiterate his position that Petitioner’s shoulder pain likely did start immediately after her vaccination. *Id.* His reasons for this were 1) she recounted immediate pain post-vaccination in her affidavit; 2) in her affidavit, she explained why she did not discuss her symptoms with Dr. Hansen on November 14, 2016 or December 14, 2016; and 3) there is no alternate explanation for her shoulder pain. *Id.*

#### **E. Dr. Abrams’ Expert Report**

Respondent filed an expert report from Dr. Abrams dated September 26, 2020 responding to Petitioner’s expert reports. Abrams Rep.

Dr. Abrams opined that Petitioner’s medical history does not meet the definition of a SIRVA for two main reasons: 1) the medical record does not contain persuasive evidence that Petitioner’s shoulder pain began within 48 hours of vaccination; and 2) Petitioner has a number of other medical conditions that are “well known causes of shoulder area pain.” Abrams Rep. at 5.

Dr. Abrams noted that Petitioner did not report shoulder pain until three months after vaccination, even though she had four medical visits during this time. Abrams Rep. at 5. Further, when she did report right shoulder pain for the first time, she stated that the pain began in January of 2017. *Id.* at 6. It was not until more than one year after vaccination that Petitioner described her shoulder pain as beginning in November of 2016. *Id.* Dr. Abrams discussed the importance of an onset close-in-time to vaccination. He stated:

The onset (typically within 48 hours) criteria is perhaps one of the most important in determining whether a vaccination event represents SIRVA as it speaks to the heart of the mechanism discussed in the SIRVA literature – an inflammatory response within the shoulder due to subacromial injection of the vaccine.

*Id.*

Dr. Abrams discussed other alternative causes of Petitioner’s shoulder pain, and stated that Petitioner’s history of right shoulder surgery, cervical spine surgery, and fibromyalgia are all well-known causes of shoulder pain. Abrams Rep. at 7-9.

Dr. Abrams opined that mild bursitis and a partial rotator cuff pathology are both extremely common findings and as such, did not support a vaccine injury in this case. Abrams Rep. at 7. He stated that one case study reported that the more than 500 patients who presented with unilateral shoulder pain had partial or full thickness rotator cuff disease on their asymptomatic shoulder. *Id.*; citing Yamaguchi et al., *The Demographic and Morphological Features of Rotator Cuff Disease*, 88-A THE JOURNAL OF BONE & JOINT SURGERY 8, 1699-1704 (2006) (filed as Ex. A, Tab 3). Dr. Abrams further noted that mild bursitis is not consistent with Dr. Natanzi's proffered medical literature, which consistently describes severe or extensive bursitis. Abrams Rep. at 7.

Dr. Abrams opined that Petitioner's findings of calcific tendonitis on MRI correlates with her rotator cuff pathology. Abrams Rep. at 8. He described calcific tendonitis as a slowly developing chronic condition, and thus was very likely present before Petitioner's November 9, 2016 vaccination. *Id.*

Dr. Abrams concluded his report by stating that Petitioner did not meet the criteria for a SIRVA injury because the medical record does not document that her pain occurred within 48 hours of vaccination. Abrams Rep. at 9. Additionally, Petitioner's other medical conditions are known to be associated with shoulder pain. *Id.*

#### **F. Dr. Natanzi's Third Expert Report**

In his third expert report, Dr. Natanzi provided additional reasoning to support onset of Petitioner's shoulder pain immediately after vaccination. He stated that the nurse who administered Petitioner's vaccine told her that her post-vaccination pain was likely related to her recent surgery. Third Natanzi Rep. at 1. He further noted that, "When the elbow surgery pain improved but her shoulder symptoms did not, she thought – as anyone would – that there must be something else going on." *Id.*

Dr. Natanzi also discussed Petitioner's history of cervical spine surgery. Third Natanzi Rep. at 2. He agreed that arthritis and radiculopathy can refer pain to the shoulder. *Id.* However, he opined that Petitioner's symptoms, given the notations in her medical records, are shoulder mediated. *Id.* Dr. Natanzi pointed to the fact that Petitioner's medical records do not mention positive cervical physical exam signs. *Id.* Based on that, he does not believe that Petitioner's history of cervical spine surgery has any bearing on her shoulder pain. *Id.*

#### **G. Dr. Natanzi's Fourth Expert Report**

Dr. Natanzi filed his fourth expert report after I issued my onset ruling. In this report, he stated that if he were to assume Petitioner's right shoulder pain began between December 14, 2016 and January 2017, "it would make a SIRVA injury much less likely." Fourth Natanzi Rep. at 2. Dr. Natanzi went on to state that in his opinion, "this case is an exception." *Id.*

In support of this position, Dr. Natanzi cited to the Arias article. Arias et al., *Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccination*, 35 VACCINE 4870-76 (2017) (filed as Ex. 14-J) (hereinafter "Arias"). Arias analyzed patients with shoulder injury after

vaccination by examining cases from FEDRA (the Spanish Pharmacovigilance System database), which is the Spanish equivalent of VAERS, and a search of published literature. Arias at 4870. Arias notes that two out of the eight FEDRA cases reported onset of shoulder dysfunction two months after vaccination. *Id.* at 4871 (Table 1).

Dr. Natanzi further opined that Petitioner did not recognize the extent of her shoulder pain due to her November 1, 2016 surgery and the pain medication she had been taking. Fourth Natanzi Rep. at 2. He concluded his report by opining that Petitioner's November 9, 2016 flu vaccination caused her to suffer a right shoulder injury. *Id.* at 2-3.

## **V. Applicable Law**

### **A. Petitioner's Burden in Vaccine Program Cases**

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. § 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. § 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825, at 3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611, at 5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement, a petitioner must establish that he suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination he received. § 11(c)(1)(C).

The most recent version of the Table identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). Pursuant to the Table, SIRVA is defined as:

shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder

resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known).

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time-frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3.

If, however, a petitioner suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, she must prove that the administered vaccine caused her injury to receive Program compensation. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a “non-Table or [an] off-Table” claim and to prevail, petitioner must prove her claim by preponderant evidence. § 13(a)(1)(A).

The Federal Circuit has indicated that a petitioner “must show ‘a medical theory causally connecting the vaccination and the injury’ to establish that the vaccine was a substantial factor in bringing about the injury.” *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec’y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Federal Circuit added that “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury.’” *Id.* The Federal Circuit subsequently reiterated these requirements in a three-pronged test set forth in *Althen v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Under this test, a petitioner is required to show by preponderant evidence that the vaccination brought about her injury by providing:

- (1) a medical theory causally connecting the vaccination and the injury;
- (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
- (3) a showing of a proximate temporal relationship between vaccination and injury.

*Id.* All three prongs of *Althen* must be satisfied. *Id.* Circumstantial evidence may be considered, and close calls regarding causation must be resolved in favor of the petitioner. *Id.* at 1280.

## **B. Law Governing Analysis of Fact Evidence**

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider “all [] relevant medical and scientific evidence contained in the record,” including “any diagnosis, conclusion, medical judgment, or autopsy or coroner’s report which is contained in the record regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition, or death,” as well as the “results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master’s discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are generally trustworthy because they “contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions,” where “accuracy has an extra premium.” *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021) citing *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec’y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825 at \*2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) *mot. for rev. denied*, 142 Fed. Cl. 247, 251-52 (2019), *vacated on other grounds and remanded*, 809 Fed. Appx. 843 (Fed. Cir. Apr. 7, 2020).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec’y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475 at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec’y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff’d per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den’d*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) (“[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.”)).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec’y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) (“like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual

predicates for its application are weak or lacking”); *Lowrie*, 2005 WL 6117475 at \*19 (“[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent”) (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness’s credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec’y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be “consistent, clear, cogent and compelling.” *Sanchez*, 2013 WL 1880825 at \*3 (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611 at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person’s failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional’s failure to document everything reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. *LaLonde v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff’d*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

### C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his or her claim. *Lampe v. Sec’y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). See *Cedillo v. Sec’y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec’y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). “The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.” *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec’y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (2010) (“uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted”). The flexible use of the *Daubert* factors to evaluate persuasiveness and reliability of expert testimony has routinely been upheld. See, e.g., *Snyder*, 88 Fed. Cl. at 743. In this matter, (as in numerous other Vaccine Program cases), *Daubert* has not

been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

#### **D. Consideration of Medical Literature**

Finally, although this decision discusses some but not all of the medical literature in detail, I have reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

### **VI. Analysis**

Although Petitioner initially alleged a Table SIRVA, my onset ruling prevents Petitioner from meeting the elements of a Table claim. Petitioner acknowledges this in her brief, stating, "Petitioner cannot establish that she suffered a Table SIRVA injury as Special Master Oler issued a Ruling in which she found that Petitioner's right shoulder pain began sometime between December 14, 2016 and January of 2017 (between 36 and 54 days – more than 48 hours post-vaccination)." Pet'r's Brief at 12. As noted above, to prevail on an "off-Table" claim, Petitioner must prove by preponderant evidence that she suffered an injury and that this injury was caused by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.

#### **A. Causation in Fact**

Even though Petitioner has not demonstrated that she suffered from a Table Injury, she may still be entitled to compensation if she can establish each element of the three part *Althen* test.

Because this case turns on an analysis of *Althen* prong three and how the timing of Petitioner's onset of pain relates to *Althen* prong one, I have focused my discussion on these areas.<sup>4</sup>

### 1. *Althen* Prong Three

The timing prong contains two parts. First, a petitioner must establish the “timeframe for which it is medically acceptable to infer causation” and second, she must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec’y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff’d without op.*, 503 F. App’x 952 (Fed. Cir. 2013).

#### a. *Onset of Petitioner’s Shoulder Pain*

In my onset ruling, I found that Petitioner developed shoulder pain sometime between December 14, 2016 and January of 2017, between 35 and 83 days<sup>5</sup> after her November 9, 2016 flu vaccine. ECF No. 55. This determination was primarily based on a review of Petitioner’s contemporaneous medical records.

Petitioner had two medical appointments that took place close-in-time to her November 9, 2016 vaccination: her medical appointment on November 14, 2016, and her appointment on December 14, 2016. Petitioner saw Dr. Hansen at both visits. Dr. Hansen specifically asked whether she was experiencing shoulder pain at both of these appointments, and both times Petitioner indicated that she was not. Ex. 4 at 4, 5.

In her affidavit, Petitioner explained she thought her shoulder pain that she experienced during this timeframe could have resulted from her November 1 surgery, as that is what the nurse who administered her flu shot told her. Ex. 7 at 2. Although this account might have been a logical one in a situation where Petitioner simply did not mention shoulder pain to Dr. Hansen, it does not provide a reasonable explanation as to why she specifically denied this pain when directly asked. As the court noted in *Lowrie*, “it must be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance.” *Lowrie*, 2006 WL, at \*7.

Further, at an appointment on April 8, 2017, when she did mention experiencing right shoulder pain, Petitioner indicated she had been experiencing pain for four months, and that there was “No known trauma.” Ex. 4 at 36. Additionally, on May 10, 2017, Petitioner presented to Dr.

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<sup>4</sup> Because Petitioner has not met her burden in establishing the first or third *Althen* prongs by preponderant evidence, I have not analyzed *Althen* prong two. *See, e.g., Alsaadeh v. Sec’y of Health & Hum. Servs.*, No. 19-1097V, 2024 WL 694072, at \*36 (Fed. Cl. Spec. Mstr. Jan. 23, 2024) (noting that “[s]ince Petitioner failed to prove *Althen* prong one, it follows that he cannot prove *Althen* prong two.”).

<sup>5</sup> When Petitioner reported her shoulder pain, she stated the pain began in January of 2017. Ex. 4 at 7. Because she did not specify when in January this occurred, I was not more specific in my onset determination. However, when calculating the onset range, it is appropriate to define the outer limit as January 31.

Hansen with complaints of right shoulder pain. Ex. 4 at 7. The HPI notes “the patient complains of right shoulder pain has been present since January of 2017 and is not the result of any accident, injury, or trauma.” *Id.* When considered in conjunction with the records from November 14 and December 14, these additional records further support the fact that Petitioner was not experiencing shoulder pain within 48 hours of her vaccination, and instead, that this pain developed in the timeframe between December 14, 2016 and January 2017.

Petitioner first indicated that her pain began in November of 2016 at a medical appointment with Dr. Hansen on December 27, 2017, more than one year after her vaccination. Ex. 4 at 9. Petitioner specifically stated that her right shoulder pain began after her flu vaccine at her initial PT consultation on January 18, 2018. Ex. 4 at 54.

While I considered Petitioner’s affidavits as well as those submitted on her behalf, I ultimately concluded that the medical records and medical histories, provided close-in-time to Petitioner’s injury were more persuasive than the medical records and affidavits presented by Petitioner and her family members between one and three years after the fact. “Written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later.” *Reusser v. Sec’y of Health & Hum. Servs.*, 28 Fed. Cl. 516, 523 (1993).

b. *35 to 83 Days Post Vaccination is not a Medically Acceptable Temporal Interval*

Petitioner has presented no persuasive evidence which suggests a shoulder injury caused by vaccination can develop this long after vaccine administration. In fact, her medical literature indicates onset of shoulder pain generally occurs within two days of vaccine administration. *See, e.g.,* M. Bodor & E. Montalvo, *Vaccination-related shoulder dysfunction*, 25 VACCINE 585-87 (2007) (filed as Ex. 14C) (documenting onset of shoulder pain within two days of vaccination); Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 VACCINE 8049-52 (2010) (filed as Ex. 14F) (noting onset of pain to be immediate or within 24 hours); Okur et al., *Magnetic resonance imaging of abnormal shoulder pain following influenza vaccination*, 43 SKELETAL RADIOL 1325-31 (2014) (filed as Ex. 14I) (documenting the period between injection and onset of pain was between immediate and two days); Barnes et al., *A “Needling” Problem: Shoulder Injury Related to Vaccine Administration*, 25 JABFM 6, 919-22 (2012) (filed as Ex. 14G) (describing a case report where one woman developed onset of shoulder pain within two hours of vaccination); Cross et al., *Don’t aim too high: Avoiding shoulder injury related to vaccine administration*, 45 AFP 5 at 303 (2016) (filed as Ex. 14K) (discussing two case reports where onset of pain was two hours and 24 hours after vaccination); Saleh et al., *Onset of Frozen Shoulder Following Pneumococcal and Influenza Vaccinations*, 14 JOURNAL OF CHIROPRACTIC MEDICINE 285-89 (2015) (filed as Ex. 14M) (presenting “three cases of shoulder stiffness with limited range of motion (ROM) that arose one day after the vaccines were administered.”).

Petitioner relies on Arias to support her position that the flu vaccine can cause the onset of shoulder pain months after her vaccination. Arias reviewed a total of 45 patients who reported shoulder injury following vaccine administration. Eight of the 45 were patients who self-reported their condition in the Spanish version of VAERS. Arias at 4871. Of these eight, two described the

onset of shoulder pain two months after vaccination. *Id.* The remaining 43 described onset from “immediate” to seven days after vaccine administration. *Id.* at 4871, 4873 (Tables 1 and 2).

This article does not increase the persuasiveness of Dr. Natanzi’s opinion. Petitioner relies on a passive surveillance system similar to VAERS where any person who believes a vaccine caused them an injury can file a report. In Arias, two people self-reported onset of shoulder pain two months after vaccination. This evidence is quite weak, and does not amount to preponderant evidence in support of *Althen* prong three. “VAERS reports are informal and unverified, and should not be confused with formal case reports in medical literature.” *L.M. by and through McClellan v. Sec’y of Health & Hum. Servs.*, No. 14-714V, 2019 WL 4072130, at \*11 n.12 (Fed. Cl. Spec. Mstr. July 23, 2019), citing *Tompkins v. Sec’y of Health & Hum. Servs.*, No. 10-261V, 2013 WL 3498652, at \*9 n.26 (Fed. Cl. Spec. Mstr. June 21, 2013). Because of this, special masters have repeatedly declined to rely on VAERS data as probative of vaccine causation. *See, e.g., Analla v. Sec’y of Health & Hum. Servs.*, 70 Fed. Cl. 552, 558 (2006) (stating that VAERS reports “offer very little information regarding causality.”); *Ryman v. Sec’y of Dept. of Health & Hum. Servs.*, 65 Fed. Cl. 35, 43 (2005) (concluding the special master did not act arbitrarily in refusing to accord substantial weight to VAERS reports). Accordingly, while I have considered the Arias article, I do not find that the self-reporting of two cases out of the 45 discussed by the authors constitutes preponderant evidence in support of the third *Althen* prong.

The Hesse article described a population based retrospective cohort study which examined the risk for subdeltoid bursitis after influenza vaccination. Hesse at 253. The study ultimately concluded that there was a small increased risk of bursitis after influenza vaccine. *Id.* In measuring the data, Hesse et al. established a risk interval of zero to two days after vaccination and a control interval of 30 to 60 days, which as they noted, “represents the background rate.” *Id.* The Hesse article provides additional support for the fact that shoulder pain occurring more than one month after vaccination is not likely attributable to the vaccine.

I and other special masters have previously considered the question of timing in SIRVA cases and have determined that a timeline between vaccination and onset of pain such as the one in the present case does not constitute a medically acceptable temporal interval. *See, e.g., Pitts v. Sec’y of Health & Hum. Servs.*, No. 18-1512V, 2023 WL 2770943, at \*14 (Fed. Cl. Spec. Mstr. Apr. 4, 2023) (concluding that petitioner did not satisfy the third *Althen* prong based on a seven day post vaccination onset of shoulder pain); *Gruszka v. Sec’y of Health & Hum. Servs.*, No. 18-1736V, 2023 WL 2583390, at \*18 (Fed. Cl. Spec. Mstr. Feb. 24, 2023) (finding that an indeterminate onset between three days and two months after vaccination precludes petitioner from meeting her burden under *Althen* prong three); *Clavio v. Sec’y of Health & Hum. Servs.*, No. 17-1179V, 2022 WL 1078175 (Fed. Cl. Spec. Mstr. Feb. 16, 2022) (determining that 59 days between vaccination and onset of shoulder pain fails to satisfy the third *Althen* prong); *Nicholson v. Sec’y of Health & Hum. Servs.*, 17-1417V, 2022 WL 14437541 (Fed. Cl. Spec. Mstr. Sept. 22, 2022) (concluding that development of shoulder pain 32 to 49 days after flu vaccine administration is not a medically acceptable temporal interval); *Mack v. Sec’y of Health & Hum. Servs.*, No. 15-149V, 2016 WL 5746367 at \*8 (Fed. Cl. Spec. Mstr. July 14, 2016) (finding that a 42 day onset between vaccination and onset of shoulder pain is not a medically acceptable timeframe to infer causation in a SIRVA case). *C.C. v. Sec’y of Health & Hum. Servs.*, No. 17-708V, 2021 WL 2182817 at \*20,

23 (Fed. Cl. Spec. Mstr. Mar. 31, 2021) (concluding that a one week onset in a SIRVA case was not medically appropriate given the theory of causation).

For these reasons, I find that Petitioner has not presented preponderant evidence in support of the third *Althen* prong.

## 2. Althen Prong One

Under *Althen*'s first prong, the causation theory must relate to the alleged injury. Petitioner must provide a "reputable" medical or scientific explanation, demonstrating that the vaccines received can cause the type of injury alleged. *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). The theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). It must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Dr. Natanzi opined that the overpenetration of the vaccine needle into the upper portion of the deltoid can cause an inflammatory response leading to bursitis and rotator cuff impingement syndrome. First Natanzi Rep. at 9. While the Vaccine Injury Table allows for the presumption that the flu vaccine can cause a SIRVA when certain criteria are met, this case does not meet the Table definition of a SIRVA due to the length of time between vaccination and onset of shoulder pain. 42 C.F.R. § 100.3(a)(XIV)(B). Each of Dr. Natanzi's three reports (authored before my ruling on onset) assumed an immediate onset of pain. His fourth report did not meaningfully discuss the new onset window of more than one month and explain how that interval was consistent with his causal theory.

As Dr. Abrams persuasively noted, the near immediate onset of pain after vaccination is particularly important because it "speaks to the heart of the mechanism discussed in the SIRVA literature – an inflammatory response within the shoulder due to a subacromial injection of the vaccine." Abrams Rep. at 6. Dr. Natanzi has not articulated a causal mechanism which would explain onset of pain more than one month after vaccine administration. Accordingly, Petitioner has failed to present preponderant evidence in support of the first *Althen* prong.

## VII. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, medical literature, the affidavits, as well as the experts' opinions, I conclude that Petitioner has not shown by preponderant evidence that she is entitled to compensation under the Vaccine Act. **Her petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**<sup>6</sup>

**IT IS SO ORDERED.**

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<sup>6</sup> Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by each filing (either jointly or separately) a notice renouncing their right to seek review.

**s/ Katherine E. Oler**

Katherine E. Oler  
Special Master